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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,463	10/20/2003	Hans Michael Ockenfels	01840.0001-US-01	4148
22865	7590	03/23/2009		
Altera Law Group, LLC 220 S 6 St Suite 1700 Minneapolis, MN 55402			EXAMINER SHAY, DAVID M	
			ART UNIT 3769	PAPER NUMBER
			MAIL DATE 03/23/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/689,463	<b>Applicant(s)</b> OCKENFELS, HANS MICHAEL	
	<b>Examiner</b> david shay	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on December 30, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, 14 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 14 and 48-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3769

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 30, 2008 has been entered.

Applicant argues that Anderson et al does not vary the UV radiation dose in different affected areas dependent on the epidermal thickness of the skin in the affected areas, asserting instead that Anderson et al determine the MED for normal skin. The examiner must respectfully disagree. Applicant's assertion relies on the disclosure at column 2, lines 19-24. However, a reference must be read for all the teachings contained therein. Thus the subsequent disclosures of Anderson et al teaching that the does applied to the plaques can be from about two to about ten times the MED for normal skin (see column 6, lines 10-24) must also be taken into account. It is also noted that this correlates with applicant's estimate that the MED for involved skin be from 2.6 to 7 times that for normal skin. Thus the fact that Anderson et al relate their treatment dose for plaques to the MED for normal skin dose not render their teachings against the claimed invention any more than it does the instant invention. Applicant's comprising-type claims are open ended and thus are read on by references that determine the dose to be applied to the "first area" and "second area" from a different area that is not affected and is separate from the "first area" and "second area". Further, the Anderson et al disclosure clearly ties the change in dosage to skin thickness, as is readily apparent from the disclosure at column 8, lines 4-65, the diagnostic ratio from the tryptophan fluorescence correlates with epidermal thickness and a separate measurement of epidermal thickness can be used as a diagnostic parameter. Thus

Art Unit: 3769

applicant's arguments that "Anderson is completely silent with regard to skin thickness" are not well founded. And, contrary to applicant's assertion Anderson et al do indeed determine, but it is done in steps: treating affected areas with a given dosage, then going over the subject again and providing additional doses to the areas determined to still need treatment. If applicant's estimation of change in dosage is correct, then the ultimate dosage applied to each area (or at least a first and second area) will vary "depending basically linearly on the first and second epidermal thickness". Applicant's claim language, as it is currently drafted, neither requires that the dosage to each area for a given treatment session be applied all at once, nor does it require that the dosage for the first area be used as a predictor for that of the second area, and that the radiation dose for the second area be computed, prior to it being applied based, on the dose required for the first area and the relative thickness of the epidermis at second area compared to that of the first and that this computation involve function that varies "basically linearly" on the relative epidermal thicknesses. As already set forth Anderson et al seek to avoid blister formation, and again, the open-ended nature of applicant's claim language coupled with the lack of requirement in the claims that the "determining" be done based any particular relationship, as the currently added language merely asserts that the relationship exists, but does not tie it in any concrete way to the "determining" step. Thus applicant's arguments are not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-7, 11, 14, and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Chernoff, Sator et al and Neigut.

Anderson et al teaches treatment of psoriasis wherein the skin is tested, e.g. by determining skin

Art Unit: 3769

thickness to determine psoriatic areas and the areas are exposed to treatment radiation, preferably so as not to cause blister formation, wherein the fluorescence generated by the treatment pulse is used to determine whether or not an additional treatment pulse should be directed to the plaque (see column 15, lines 37-48). Chernoff teaches a device and method for treating the skin wherein the skin depth is determined at each point of treatment and the treatment laser power is adjusted for the depth at each point. Sator et al teach that PUVA treated skin experiences accelerated thinning, which is correlated with the PUVA compared to the skin of people who have not undergone PUVA and that ultrasound is a sensitive and non-invasive method for determining skin thickness. Neigut teaches that psoriatic plaques reduce with treatment (see column 13, lines 14-34). It would have been obvious to the artisan or ordinary skill to use ultrasound to measure the skin thickness of patients in the method of Anderson et al, since this is a sensitive and non-invasive measure, as taught by Sato et al, and to employ the laser-ultrasound cooperation steps of Chernoff in the method, since this would enable the dosages to be minimized for each patient by preventing the dosing of unaffected skin, and to vary the dosage with each treatment, since treatments reduce the plaques, thus reducing the required dosage to treat them under the regimen of Anderson et al, thus producing a device and method such as claimed.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Chernoff, Sator et al, and Neigut as applied to claims 1, 2, 4-7, 11, 14, and 48-52 above, and further in combination with Mueller et al. Mueller et al teach the incorporation of a laser and ultrasound applicator in a single instrument. It would have been obvious to the artisan or ordinary skill to provide the laser and ultrasound applicator in the

Art Unit: 3769

combined method of Anderson et al in combination with Chernoff and Sator et al, since the separated ultrasound and laser applicators and combined applicators are equivalents, as shown by Mueller et al, or, alternatively, to employ the combined method of Anderson et al in combination with Chernoff and Sator et al in the method of Mueller et al, since Mueller et al discuss no therapy for any particular condition and in either case, to employ a mirror arm to conduct the radiation, since this is equivalent to the use of fiber optics and can more efficiently transmit ultraviolet light, official notice of which is hereby taken, thus producing a device such as claimed.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Chernoff, Sator et al, and Neigut as applied to claims 1, 2, 4-7, 11, and 14 above, and further in combination with Bonis et al. Bonis et al teach increasing the dosage of UV light in psoriasis plaques that do not respond to a base level of therapy, and continuing the increase until a response is seen. It would have been obvious to the artisan of ordinary skill to employ the dosage increase technique of Bonis et al in the combined method of Anderson et al in combination with Chernoff and Sator et al, since this yields better results, as taught by Bonis et al, thus producing a method and device such as claimed.

Applicant's arguments filed December 30, 2008 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

Art Unit: 3769

after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3769

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769